

(c) *Application procedure.* Applications for blanket certificates must be accompanied by the fee prescribed in § 381.207 of this chapter or a petition for waiver pursuant to § 381.106 of this chapter, and shall state:

\* \* \* \* \*

(d) *Effect of certificate.* (1) Any certificate granted under this section will authorize the certificate holder to engage in transactions of the type authorized by subparts C and D of this part.

\* \* \* \* \*

(e) *General conditions.* (1) Except as provided in paragraph (e)(2) of this section, any transaction authorized under a blanket certificate is subject to the same rates and charges, terms and conditions, and reporting requirements that apply to a transaction authorized for an intrastate pipeline under subparts C and D of this part.

\* \* \* \* \*

(g) *Hinshaw pipeline without blanket certificate.* A Hinshaw pipeline that does not obtain a blanket certificate under this section is not authorized to sell or transport natural gas as an intrastate pipeline under subparts C and D of this part.

\* \* \* \* \*

114. Sections 284.225 and 284.226 are removed and reserved.

115. In § 284.227, paragraph (d) is removed, and paragraphs (e), (f), and (g) are redesignated (d), (e), and (f).

#### **Subpart J—Blanket Certificates Authorizing Certain Natural Gas Sales by Interstate Pipelines**

##### **§ 284.288 [Removed]**

116. Section 284.288 is removed and reserved.

#### **Subpart L—Certain Sales for Resale by Non-interstate Pipelines**

117. In § 284.402, paragraph (c)(1) is revised to read as follows and in the first sentence of paragraph (c)(2) the word “criteria” in paragraph (c)(2) is removed, and the word “criterion” is added in its place:

##### **§ 284.402 Blanket marketing certificates.**

\* \* \* \* \*

(c)(1) The authorization granted in paragraph (a) of this section will become effective for an affiliated marketer with respect to transactions involving affiliated pipelines when an affiliated pipeline receives its blanket certificate pursuant to § 284.284.

\* \* \* \* \*

[FR Doc. 95-653 Filed 1-12-95; 8:45 am]

BILLING CODE 6717-01-P

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

#### **21 CFR Part 892**

[Docket No. 94N-0345]

#### **Medical Devices; Classification of Transilluminators (Diaphanosopes or Lightscanners) for Breast Evaluation**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to classify the transilluminator (diaphanoscope or lightscanner) for breast evaluation into class III (premarket approval). The agency is also publishing in this document the recommendations of the Obstetrics and Gynecology Devices Panel regarding the classification of the device. After considering public comments on the proposed classification, FDA will publish a final regulation classifying the device. This action is being taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) and the Safe Medical Devices Act of 1990 (the SMDA).

**DATES:** Written comments by April 13, 1995. FDA proposes that any final regulation that may issue based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Robert A. Phillips, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 1390 Piccard Dr., Rockville, MD 20850, 301-594-1212.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

The act, as amended by the 1976 amendments (Pub. L. 94-295) and the Safe Medical Devices Act of 1990 (Pub. L. 101-629), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of

devices are class I (general controls), class II (special controls), and class III (premarket approval). Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments) are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendations for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device.

A device that is first offered in commercial distribution after May 28, 1976, and which FDA determines to be substantially equivalent to a device classified under this scheme, is classified into the same class as the device to which it is substantially equivalent. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 of the regulations (21 CFR part 807). A device that was not in commercial distribution prior to May 28, 1976, and that has not been found by FDA to be substantially equivalent to a legally marketed device, is classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking proceedings.

In 1980, when other obstetric and gynecological devices were classified (45 FR 12684 through 12720, February 26, 1980), FDA was not aware that transilluminators, also known as lightscanners or diaphanosopes, for breast evaluation were preamendments devices, and inadvertently omitted them from the classification process. Based upon the recommendations the Obstetrics and Gynecological Devices Panel made during its January 11, 1991, meeting (Ref. 24), FDA is now proposing to classify the transilluminator for breast evaluation into class III, thereby requiring each manufacturer of the device to submit to FDA a PMA by a date to be set in a future regulation under section 515(b) of the act (21 U.S.C. 360e(b)). Specifically, a preamendments class III device may be commercially distributed without an approved PMA until 90 days after FDA issues a final rule requiring premarket approval of the device or 30 months after classification of the device under section 513 of the act, whichever is later. Each application must include sufficient valid scientific evidence to provide reasonable assurance that the device is safe and effective under the conditions of use prescribed,

recommended, or suggested in its proposed labeling.

## II. The Obstetrics and Gynecology Devices Panel Recommendations

The Obstetrics and Gynecology Devices Panel, an FDA advisory committee, made the following recommendations regarding the classification of the transilluminator for breast evaluation.

### A. Identification

A transilluminator, also known as a lightscanner or diaphanoscope, is an electrically powered device that uses low intensity emissions of visible light and near-infrared radiation (approximately 700 to 1050 nanometers (nm)), transmitted through the breast, to visualize translucent tissue for the diagnosis of cancer, other conditions, diseases, or abnormalities (Ref. 24).

### B. Recommended Classification

Class III (premarket approval). The Obstetrics and Gynecology Devices Panel recommended that the transilluminator for breast evaluation be classified into class III and that a regulation requiring submission of premarket approval applications for this device be a high priority. The Obstetrics and Gynecology Devices Panel further recommended that, at this time, the device should not be used for breast examinations, either alone or in conjunction with other techniques.

### C. Summary of Reasons for Recommendation

The Obstetrics and Gynecology Devices Panel recommended that transilluminator devices for breast evaluation be classified into class III because the Panel believes that premarket approval is necessary to provide reasonable assurance of the safety and effectiveness of the device. The Obstetrics and Gynecology Devices Panel concludes that there are no published studies or clinical data demonstrating the safety and effectiveness of the device. The Obstetrics and Gynecology Devices Panel also believes that the device presents a potential unreasonable risk of illness or injury to the patient if the clinician relies on the device. Although the device's illumination level, wavelength, and image quality can be controlled through tests and specifications, the Obstetrics and Gynecology Devices Panel believes that insufficient evidence exists to determine that special controls can be established to provide reasonable assurance of the safety and effectiveness of the device for its intended use. The Obstetrics and

Gynecology Devices Panel recommends, therefore, that the device be subject to premarket approval to ensure that manufacturers of this device demonstrate the device's safety and effectiveness in order to market the device.

### D. Summary of Data Upon Which the Recommendation is Based

The Obstetrics and Gynecology Devices Panel based its recommendation on the review of the studies cited in this document, on expert testimony presented to the Obstetrics and Gynecology Devices Panel, and on the Panel members' personal knowledge of, and experience with, the device.

### E. Risks to Health

The following risks are associated with the use of transilluminators: Missed diagnosis; delayed diagnosis; delayed treatment; electrical shock; and optical radiation. Due to the transilluminator's questionable performance, the use of the device could result in missed or delayed diagnosis of breast cancer. Such misdiagnoses could result in more traumatic treatment to the patient and a potentially higher risk of death.

## III. Proposed Classification

FDA agrees with the Obstetrics and Gynecology Devices Panel's conclusions and recommendations. The National Cancer Institute (NCI) also agrees that transilluminators have not been proven effective for diagnosis of cancer. In a September 1990 issue of *Cancer Facts*, the NCI states, "Although this technique has been improved over the years, at this time transillumination is not an effective technique for the detection of early breast cancer," and, "Transillumination is especially poor at finding small tumors (less than 1 centimeter)." NCI supports the idea of further research, but states, " \* \* \* at this time, transillumination has no role in breast cancer screening" (Ref. 1).

A major study of transillumination involving 2,763 patients was conducted by the National Institutes of Health in the late 1980's (Ref. 2). In a section entitled "Combined Modality Results," the study authors concluded: "While the accuracy of clinical exam [in detecting cancer] is 0.67 and that of lightscanning is 0.57, there is no statistically significant difference between them." That is, there was no difference between the use of lightscanning and clinical examination (palpation). They also stated, "When the results of lightscanning, mammography and physical exam are added, no

additional benefit is seen" as a result of light scanning. This study indicates that transilluminators, at this time, do not have clinical benefits as an alternative to mammography or as an adjunctive diagnostic tool to mammography.

Following the January 1991 Obstetrics and Gynecology Devices Panel meeting, FDA undertook a literature search to determine if any new and significant studies had been performed, which would affect the proposed classification. The agency reviewed approximately 20 references (Refs. 4 through 23) published since 1988. None of these studies recommend the device for routine clinical use.

One of the largest studies conducted in a clinical setting was a multicenter study in Sweden involving 2,568 women (Ref. 3). The study concluded that lightscanning, as utilized in the study, is inferior to mammography and produced a large number of false positive results.

In summary, FDA's review of recent technical and clinical papers did not reveal any data that would influence the agency to adopt any classification other than class III.

FDA believes that insufficient information exists to determine that general controls, or special controls, such as postmarket surveillance, the development of guidelines, the establishment of a performance standard, or other actions will provide reasonable assurance of the effectiveness of the transilluminator for breast evaluation. FDA believes that use of the transilluminator for breast evaluation presents a potential health risk because of the possibility of misdiagnosis. The evident failure of transilluminator evaluations to detect breast cancer in its earliest stages, when the chance for a cure is highest, requires FDA to place this preamendment device in class III in order to require manufacturers to provide data establishing reasonable assurance of the device's safety and effectiveness.

FDA concurs with the Obstetrics and Gynecology Devices Panel's recommendation that the agency should give high priority to a regulation to establish premarket approval requirements for the transilluminator because of the public health considerations involved.

Since the Obstetrics and Gynecology Devices Panel meeting of January 1991, FDA has warned manufacturers of breast transillumination devices that these devices are in violation of the act because their labeling is false or misleading and fails to bear adequate direction for use under section 502(a) and (f)(1) of the act (21 U.S.C. 352(a)

and (f)(1)). FDA took this position following the Obstetrics and Gynecology Devices Panel meeting, after considering the Obstetrics and Gynecology Devices Panel's recommendation, after further evaluation of the available scientific literature, and following further consultation with outside medical experts. FDA concluded that the transillumination devices are not clinically effective for the diagnosis or detection of breast cancer or other breast abnormalities or conditions, and that the use of the technique may contribute to the delay of detection of lesions in the early stages of cancer, when the disease is most treatable.

At this time, therefore, the distribution of breast transillumination devices or any multipurpose transillumination device that is labeled, promoted, or intended for use in the breast is in violation of the law, regardless of whether the device is labeled for independent use or adjunctive use with mammography. FDA has initiated enforcement actions against manufacturers who have continued to distribute transilluminators.

When these devices become subject to the premarket approval process, the manufacturer of each individual device will have an opportunity to demonstrate the safety and effectiveness of the device for its indicated use. Any further decision on adjunctive use versus stand alone use will be based on valid scientific data presented by manufacturers in the PMA's they submit at that time.

FDA intends to publish pursuant to section 515(b) of the act, a proposed rule to establish the effective date of the requirement for premarket approval for transilluminators. Such a rule will be published after the effective date of a final classification regulation based on this proposed rule. A PMA may be required 30 months after the effective date of the final rule classifying the device in class III under section 513 of the act or 90 days after publication of the final rule requiring premarket approval under section 515(b), whichever is later. After the establishment of an effective date for the requirement of PMA submissions for these devices, any transilluminators for use on breast tissue that are being marketed without a PMA will be considered adulterated under section 501(f)(2) of the act (21 U.S.C. 351(f)(2)). However, as noted earlier, FDA has determined, in light of scientific data that has become available, that transilluminators for use in the breast are already misbranded under sections

502(a) and 502(f)(1) of the act and should not be marketed at this time.

FDA concludes that because the transilluminator is a diagnostic imaging device, it would be more appropriately classified as a radiological device. The agency therefore proposes to classify it in part 892 (21 CFR part 892) of the regulations (radiology devices) instead of part 884 (21 CFR part 884) of the regulations (obstetrical and gynecological devices).

#### IV. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. "Transillumination Not Effective for Early Breast Cancer Detection," National Cancer Institute, Office of Cancer Communications, September 1990.
2. "Breast Cancer Diagnosis by Lightscan (Revised)," final report, Grant No. CA37970-04, Myron Moskowitz, principal investigator, Breast Imaging Center, University of Cincinnati Medical Center, December 1989.
3. Alveryd, A. et al., "Lightscanning Versus Mammography for the Detection of Breast Cancer in Screening and Clinical Practice: A Swedish Multicenter Study," *Cancer (U.S.A.)*, vol. 65/8 1671-1677, April 15, 1990.
4. Key, H., P. C. Jackson, and P. N. T. Wells, "New Approaches to Transillumination Imaging," *Journal of Biomedical Engineering*, vol. 10, No. 2, 113-118, 1988.
5. Zhou, X., and R. Gordon, "Detection of Early Breast Cancer: An Overview and Future Prospects," *Critical Reviews in Biomedical Engineering*, vol. 17, issue 3, 230-232, 1989.
6. Adams, D. L., "Reassessment of Transillumination Light Scanning for the Diagnosis of Breast Cancer," National Center for Health Services Research and Health Care Technology Assessment, U.S. Department of Health and Human Services, Public Health Service, Springfield, VA. Available from National Technical Information Services, Health Technology Assessment Report; No. 2, 1988.
7. Hebden, J. C., and R. A. Kruger, "Transillumination Imaging Performance: A Time-of-Flight-Imaging System," *Medical Physics*, vol. 17, No. 3, 1990.
8. Jarlman, O., R. Berg, and S. Svanberg, "Time-Resolved Transillumination of the Breast," *Acta Radiologica*, vol. 33, 1992.
9. Key, H., E. R. Davies, P. C. Jackson, and P. N. T. Wells, "Optical Attenuation Characteristics of Breast Tissue at Visible and Near Infrared Wavelengths," *Physics in Medicine and Biology*, vol. 36, No. 5, 1991.
10. Peters, V. G., D. R. Wyman, M. S. Patterson, and G. L. Frank, "Optical Properties of Normal and Diseased Human Breast Tissue in the Visible and Near Infrared," *Physics in Medicine and Biology*, vol. 35, No. 9, 1990.
11. Profio, A. E., G. A. Navarro, and O. W. Sartorius, "Scientific Basis of Breast Diaphanography," *Medical Physics*, vol. 16, No. 1, 1989.

12. Key, H., E. R. Davies, P. C. Jackson, and P. N. T. Wells, "Monte Carlo Modelling of Light Propagation in Breast Tissue," *Physics in Medicine and Biology*, vol. 36, No. 5, 1991.

13. Navarro, G. A., and A. Edward Profio, "Contrast in Diaphanography of the Breast," *Medical Physics*, 15(2), March/April 1988.

14. Watmough, D. J., "Breast Compression to Increase the Sensitivity of Lightscanning for the Detection of Carcinoma: Potential Hazard?" Letter to the editor, *Journal of Biomedical Engineering*, vol. 14, March 1992.

15. Economou, S. G. et al., eds., *Imaging Techniques in Adjuncts to Cancer Surgery*. Lea and Febiger, 51-126, 1991.

16. "Is Lightscanning a Viable Alternative to Mammography for Detecting Breast Cancer?" in News Briefs, *New York State Journal of Medicine*, June 1990.

17. Jarlman, O., I. Anderson, G. Balldin, and S. A. Larsson, "Diagnostic Accuracy of Lightscanning and Mammography in Women with Dense Breasts," *Acta Radiologica* 33, fasc. 1, 1992.

18. He, Ping, Kaneko, Maseo, et al., "Breast Cancer Diagnosis by Laser Transmission Photo-scanning with Spectro-Analysis" (Report 4), *Radiation Medicine*, vol. 8 No. 1, 1-5, 1990.

19. Braddick, M. R., "Audit of a Breast Cancer Screening Programme Using Clinical Examination and Lightscanning," *Health Bulletin* 49/6 299-303, November 1991.

20. Gordenne, W., and E. Bauduin, "Diagnostic Accuracy of New Imaging Techniques in Breast Diseases," *Journal Belge de Radiologie*, 72:35-38, 1989.

21. Heywang-Kobrunner, "Nonmammographic Breast Imaging Techniques," *Current Opinion in Radiology*, vol. 4, 146-154, 1992.

22. Jarlman, O. et al., "Relation Between Lightscanning and the Histologic and Mammography Appearance of Malignant Breast Tumors," *Acta Radiologica* 33, 63-68, fasc. 1992.

23. Monsees, B., J. M. Destouet, and D. Gersell, "Lightscanning of Monpalpable Breast Lesions: Reevaluation," *Radiology*, 167:352, 1988.

24. Obstetrics and Gynecology Devices Obstetrics and Gynecology Panel, Forty-fifth Meeting, Transcript and Meeting Minutes, January 11, 1991.

#### V. Environmental Impact

The agency has determined under 21 CFR 25.24(e)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

#### VI. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory

approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the agency believes only a small number of firms will be affected by this rule when finalized, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

## VII. Request for Comments

Interested persons may, on or before April 13, 1995, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

### List of Subjects in 21 CFR Part 892

Medical devices, Radiation protection, X-rays.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 892 be amended as follows:

### PART 892—RADIOLOGY DEVICES

1. The authority citation for 21 CFR part 892 continues to read as follows:

**Authority:** Secs. 501, 510, 513, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

2. New § 892.1990 is added to subpart B to read as follows:

#### § 892.1990 Transilluminator for breast evaluation.

(a) *Identification.* A transilluminator, also known as a diaphanoscope or lightscanner, is an electrically powered device that uses low intensity emissions of visible light and near-infrared radiation (approximately 700–1050

nanometers (nm)), transmitted through the breast, to visualize translucent tissue for the diagnosis of cancer, other conditions, diseases or abnormalities.

(b) *Classification.* Class III (premarket approval).

(c) *Date premarket approval (PMA) or notice of completion of a product development protocol (PDP) is required.* The effective date of the requirement for premarket approval has not been established. See § 892.3.

Dated: December 23, 1994.

**D.B. Burlington,**

*Director, Center for Devices and Radiological Health.*

[FR Doc. 95–971 Filed 1–12–95; 8:45 am]

BILLING CODE 4160–01–F

## DEPARTMENT OF THE TREASURY

### Bureau of Alcohol, Tobacco and Firearms

#### 27 CFR Parts 4, 5, and 7

[Notice No. 804; Re Notice No. 803]

RIN: AB32

#### Alteration of Labels on Containers of Distilled Spirits, Wine, and Beer (CRD–94–8)

**AGENCY:** Bureau of Alcohol, Tobacco and Firearms (ATF), Department of the Treasury.

**ACTION:** Corrected Notice of Proposed Rulemaking.

**SUMMARY:** On January 4, 1995, the Bureau of Alcohol, Tobacco and Firearms (ATF) published a notice of proposed rulemaking (Notice No. 803, 60 FR 411) in the **Federal Register**. Because the notice contained errors which could cause confusion to the public, ATF is reprinting the entire corrected text here, in this correction notice, as it should have appeared in Notice No. 803. The original text of Notice No. 803 should be disregarded; instead, all interested parties should refer to the reprinted text in this document. ATF is extending the comment period accordingly to allow 60 days from the date of this correction notice.

ATF is proposing to amend the regulations in 27 CFR Parts 4, 5, and 7 which implement section 105(e) of the Federal Alcohol Administration Act of 1935, which makes it unlawful for any person to alter, mutilate, destroy, obliterate, or remove any mark, brand or label on wine, distilled spirits, or malt beverages held for sale in interstate or foreign commerce or after shipment therein. The proposed amendments will

eliminate a requirement that persons obtain ATF approval before relabeling wine and malt beverage products. Instead, persons who intend to relabel wine, malt beverage, or distilled spirits products would be required to notify ATF, in writing, of their intent to relabel. The proposed amendments will make it unlawful to relabel a distilled spirits, wine, or malt beverage container if the effect of such action is to remove from the container or label any information required by ATF regulations, or a product identification code placed on the product by the producer for tracing purposes.

**DATES:** Written comments must be received on or before March 14, 1995.

**ADDRESSES:** Send written comments to: Chief, Wine, Beer, and Spirits Regulations Branch, Bureau of Alcohol, Tobacco and Firearms, P.O. Box 50221, Washington, DC 20091–0221. [Attn: Notice No. 804.]

**FOR FURTHER INFORMATION CONTACT:** Daniel J. Hiland, Wine, Beer, and Spirits Regulations Branch, Bureau of Alcohol, Tobacco and Firearms, 650 Massachusetts Avenue, NW., Washington, DC 20226 (202–927–8210)

#### SUPPLEMENTARY INFORMATION:

##### Background

Several producers and importers of alcoholic beverages have complained to the Bureau of Alcohol, Tobacco and Firearms (ATF) that product identification code markings placed on containers and labels of wines and distilled spirits by producers for tracing purposes are being removed or mutilated after the product has left the producer's premises. Such alterations of labels or packages have been permitted in foreign trade zones and Customs bonded warehouses, because ATF regulations do not specifically address such activities, and because product identification codes are not mandatory information under ATF regulations. However, the effect of such action is to make it impossible for the producers to rely on production codes to trace mislabeled, adulterated, or unsafe products.

#### Federal Alcohol Administration Act

Section 105(e) of the Federal Alcohol Administration Act (FAA Act), 27 U.S.C. § 205(e), authorizes ATF to prescribe regulations relating to the packaging, marking, branding, labeling, and size and fill of containers as will prohibit deception of the consumer with respect to such products or the quantity thereof.

In order to prevent the sale or shipment or other introduction of